or several hygroscopic agents and a direct compression soluble diluent. Said technology is registered as Flashtab® by Prographarm and is described in the patent EP 0548356.

d) Obtaining orally disintegrating tablets that disintegrate in the oral cavity in less than 60 seconds, and which contain spray-dried mannitol, crospovidone and other excipients, by direct compression. Said technology is described in the patent application WO 00/57857 by Yuhan Corporation.

However, all the above processes for obtaining tablets involve, to a greater or lesser extent, the following disadvantages:

- A high content of insoluble excipients or microencapsulated active ingredients that give the formula a gritty feel after they have been disintegrated in the oral cavity and, consequently, problems with palatability.
- Excessively long disintegration times in comparison with oral lyophilisates or wafers, which, in general, dissolve in less than 10 seconds.
- Insufficient mechanical resistance to resist conventional packaging and transport operations.

Description of the invention

A first aspect of the present invention is to provide orally administered tablets that disintegrate quickly in the oral cavity, in particular, in less than 30 seconds, and which can hardly be noticed on the tongue after their disintegration.

A second aspect of the present invention is to provide a

process for obtaining said orally disintegrating tablets via direct compression, where direct compression is understood as a manufacturing process that involves sieving, mixing and compression operations only.

Detailed description of the invention

Surprisingly, the present invention has revealed that by using a diluent of high dissolution rate and high compressibility, and limiting the proportion and size of the particle of the insoluble ingredients, mixtures with optimum compressibility can be obtained. These mixtures enable the obtaining of orally disintegrating tablets which disintegrate in the mouth in less than 30 seconds, preferably less than 20 seconds, once they come into contact with saliva in the oral cavity, and which are hardly noticed on the tongue.

A further advantage is that the tablets described in the invention have sufficient mechanical resistance to resist the production and distribution operations, unlike other fast disintegration formulas such as oral lyophilisates, tablets of saccharide based shearform floss and wafers. The tablets of the invention have a friability of below 0.5%, preferably below 0.2%, as specified by Ph. Eur. 2.9.7. These friability values enable packaging in any kind of package using conventional machinery, and do not require any special care to be taken in the intermediate bulk storage of the tablets or in the feed systems used in the packaging operation.

As a result, the first aspect of the present invention relates to an orally administered tablet as defined in the attached claims 1 to 11.

A priori, there are no limitations to the active ingredients in this invention, although the active

- A disintegration time in the oral cavity of below 30 seconds, preferably below 20 seconds.
- An apparent density from 1.1 to 1.3 g/ml.

The apparent density of the tablets is calculated by means of the division of the mass (m) by the volume (.e.g. $V=\pi \cdot r^2 \cdot h$, if the tablet is flat and round like the preferable shape proposed in this invention, where r is the radius and h the thickness of the tablet). It has been shown that the apparent densities of the tablets obtained with the compositions of the present invention correlate to the resistance to breakage of the tablets and to their disintegration time in the mouth. It has also been shown that tablets with apparent densities from 1.1 to 1.3 g/ml make it possible to guarantee the specifications of friability and disintegration, which is the aim of the present invention.

It has also been observed that in order to guarantee fulfilment of the specification of the disintegration time in the oral cavity, the tablets should disintegrate in less than 40 seconds in the *in vitro* disintegration test described in the tablet characterisation section of the Experimental Section of the present invention.

As mentioned previously, the present invention also relates to a process for obtaining said orally disintegrating tablets comprising direct compression. The tablets described in the invention are obtained by compression of a powder blend into solid form, which dimensions and shape enable even further minimisation of disintegration time.

In particular, the process for obtaining an orally administered tablet as previously defined comprises the

CLAIMS

1. Orally administered tablet that disintegrates quickly in the oral cavity in less than 30 seconds, comprising:

i) Spray-dried mannitol in a proportion of at least 59.5%;

ii) active ingredient in a proportion below or equal to 10%, as a fine powder in which at least 90% in weight of the active ingredient has a particle size less than 100 µm;

iii) Microcrystalline cellulose in a proportion from 10 to 18%, with an average particle size of approximately 50 µm where at least 99% in weight of microcrystalline cellulose has a particle size below 250 µm;.

iv) Sodium croscarmellose in a proportion from 1 to 4%; and

v) A lubricant agent in a proportion from 0.5 to 2% in weight,

where, unless specified otherwise, the percentages are expressed in weight of the total weight of the tablet.

2. Orally administered tablet according to claim 1, characterised in that it has a friability below 0.5% according to Ph. Eur. 2.9.7.

3. Orally administered tablet according to claim 2, characterised in that it has a friability below 0.2% according to Ph. Eur. 2.9.7.

4. Orally administered tablet according to claim 1, characterised in that it has an apparent density from 1.1 to 1.3 g/ml.

5. Orally administered tablet according to claim 1, characterised in that it has a flavouring agent in a proportion from 0.5 to 2% in weight of the total weight of the tablet.

6. Orally administered tablet according to claim 5, characterised in that it has an artificial sweetener in a proportion from 0.5 to 2% in weight of the total weight of the tablet.

7. Orally administered tablet according to claim 1, characterised in that it has a humidity adsorbing agent in a proportion from 0.1 to 0.5% in weight of the total weight of the tablet.

8. Orally administered tablet according to claim 1, characterised in that it has an anti-adherent agent in a proportion from 0.5 to 2% in weight of the total weight of the tablet.

9. Orally administered tablet according to claim 1, characterised in that the proportion of insoluble elements is below 20% in weight of the total weight of the tablet.

10. Orally administered tablet according to any of previous claims, characterised in that it has a round shape, flat, bevelled with a thickness from 1,8 to 2.2 mm.

11. Orally administered tablet according to claim 10, characterised in that it disintegrates quickly in the oral cavity in less than 20 seconds.

12. Process for obtaining an orally administered tablet as defined in any of claims 1 to 11, characterised